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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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DAVID E BROOKS
HAMILTON BROOK SMITH AND REYNOLDS
TWO MILITIA DRIVE
LEXINGTON MA 02173-4799

| EXAMINER | |
|---|---|
| SAUNDERS, D | |
| ART UNIT | PAPER NUMBER |
| 1644 | 5 |

DATE MAILED: 11/30/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☑ Claim(s) 1-20 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-12, 14-15, 18-20 is/are rejected.
☑ Claim(s) 13, 16-17 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
☑ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**SEE OFFICE ACTION ON THE FOLLOWING PAGES**

The amendment of 1/15/01 (Paper 11) has been entered. Claims 1-9 and 11-20 are pending and under examination.

The following correction has been entered into the file record:

In the previous Office Action (Paper 9) at page 2, line 11, changed "Claim 1 is" to read--claims 1-9 and 11-20 are--. This change has been entered in red ink and initiated and dated by the examiner; applicant should likewise correct his copy.

The above noted change is consistent with the examiner's statement at page 4, second paragraph that "all dependent claims are rejected over the teachings of Wisdom". Applicant's response has also been written on the basis that all of the dependent claims were thus rejected (See paper 11, page 3).

Claims 1-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wisdom (Ed.) (Peptide Antigens . . .) alone or in view of Zegers et al (Immunological Recognition . . . ).

Applicant's amendment of claim 9 to recite "the antigen is a T-cell epitope" instead of "The antigen comprises a T-cell epitope" fails to overcome the prior art. As the examiner previously noted (Paper 9, page 3, last paragraph) Wisdom does teach the steps which would determine the minimum size of the epitope in peptides identified as containing epitopes. Thus the teachings of Wisdom encompass not only the screening for antigenic fragments which comprise T-cell epitopes, but also the screening for the actual T-cell epitopes within such fragments.

Furthermore, as the examiner has previously noted (Paper 9, page 2) the instant claims are of sufficient breadth to merely encompass the identification of one or more synthetic peptide fragments (e.g. as in the method of Wisdom in chapter 7, or Zegers et al p. 108) or one or more proteolytic fragments (as in the cathepsin D preparation method of Zegers et al p. 108), from among a collection of such synthetic or proteolytic fragments as containing T-cell epitopes. The term "vaccine" throughout the claims represents a mere intended use of the candidate composition or collection of compositions with which one commences the claimed method in step (a). In any event the collection of synthetic peptides (Wisdom or Zegers et al) or proteolytic fragments (Zegers et al) may be properly considered as a collection of candidate vaccines, since the purpose of the taught screening for T-cell epitopes, in each reference, would have been for the identification of those peptides/fragments which contain T-cell epitopes that would be used in a vaccine, following further testing of the identified peptide in animals/humans.

Applicant's urgings (Paper 11, pages 5-6, 9-10) have argued that Wisdom only teaches synthetic peptide antigens derived from a protein of a known amino acid sequence, while applicant's invention can screen more complex compositions. While this may be true, applicant's claims do not exclude the use of synthetic peptides or of proteolytically derived peptides (e.g. Zegers et al, p. 108, col. 1, second full paragraph). Further applicant admits (paper 11, page 5) that his candidate vaccines encompass "peptides derived from a pathogen". Therefore, the synthetic or proteolytically derived peptides of the prior art are within the scope of what applicant intends to use as the candidate vaccine compositions in step (a) of each claim.

Applicant has further urged (page 6, that the synthetic peptides of Wisdom would not be useful as vaccines and that Wisdom does not consider the use of more complex vaccines. This argument is not relevant since, as noted further supra applicant's claims can be properly interpreted as screening a mere collection of peptides/fragments of a protein for those which comprise or constitute T-cell epitopes, irrespective of whether what is identified is useful as a vaccine. The claim can be properly interpreted in terms of the actual steps conducted, and not in terms of the intended use of the composition or compositions one employs in the first step and identifies/selects in the penultimate or ultimate step.

The examiner further notes that even if weight is given to the term "vaccine composition", then any further testing of peptides in animals/humans taught by Wisdom or Zegers et al need not identify an efficacious vaccine. Nothing in the concluding language of any claim requires that the assessing conducted in animal or human subjects yield a positive result. Thus even if all results of immunization with peptides showed ineffective results, the limitations of the claim would still have been met.

For the reasons set forth in the above two paragraphs, the examiner does not consider it necessary for the prior art to have enabled the production of any effective peptide based vaccine, though Wisdom does in fact point to vaccines in which a peptide is co-administered with a polyclonal immune cell activator (page 86, first full paragraph).

Applicant has further urged (pages 8 and 10) that neither Wisdom nor Zegers et al present an enabling disclosure as to how one can identify T-cell epitopes. This assertion is without basis,

since what Zegers et al teach (page 108, col. 1, first and second full paragraphs) is a report of what has been accomplished in the art in terms of experimentally identifying peptides containing T-cell epitopes, rather than a speculative suggestion as to how one might go about identifying T-cell epitopes. Applicant is merely blowing a smoke screen by arguing (page 8) that Wisdom's screening method can yield "false negative results"; even if this is granted, it is to be noted that there is nothing in applicant's own disclosure of claims which would rule out similar "false negative results", since nothing requires that the claimed in vitro method results in the assessing/selecting method that is positive for every candidate vaccine which might, in fact, be efficacious in vivo.

Applicant has urged (pages 8 and 9) that "Wisdom has only taught a sketchy general method of epitope mapping using synthetic peptides "and that Wisdom has not listed or suggested the steps of the claims. It is to be noted that, however, that the examiner has reasonably shown (paper 9, page 3) that all of the steps of the claimed method would have been readily deduced. For example, in the "sketchy" scheme presented in Figure 1 (page 184), for the box labled as "In vitro assays using T-cell clones, cell lines, or separated cells", one would have reasonably deduced that these assays would rely upon the in vitro use of antigen presenting cells (APCs), since Wisdom teaches (p. 182) that APC's are necessary for presenting peptide to T-cells. One would have also reasonably deduced that Thymidine incorporation, lysis of target cells, or production of cytokines would be used to assay the T-cells response, as taught at pages 212-213.

Therefore, the examiner has shown that one would have reasonably deduced the steps of the instantly claimed method from the teachings of Wisdom.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to D. Saunders at telephone number (703) 308-3976.

Saunders:mv

April 13, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644